SCOPE: Centene Corporate Pharmacy Solutions, Health Plan Pharmacy Departments, Centene Corporate Pharmacy and Therapeutics Committee, Health Plan Pharmacy and Therapeutics Committees, and Envolve Pharmacy Solutions.

PURPOSE:
To describe the Centene Health Plan Pharmacy Program.

POLICY:
It is the policy of Centene Health Plan to develop and maintain a comprehensive, high quality pharmacy program.
Centene Corporation
Health Plan

Pharmacy Program
Description
I.  INTRODUCTION

A.  PURPOSE
The purpose of the Pharmacy Program at the Centene Health Plans is to provide access to pharmaceutical services to eligible members, and to ensure that these services are a covered benefit, medically necessary, appropriate to the patient’s condition, rendered in the appropriate setting, and meet professionally recognized standards of pharmaceutical care. In addition, the Pharmacy Program at the Centene Health Plan seeks to educate providers regarding the cost effective usage of drugs and to provide useful feedback about current prescribing patterns to improve the quality of patient care.

B.  SCOPE
The Pharmacy Program applies to all Centene Health Plan members eligible to receive a pharmacy benefit. The scope of the program is to:

- Ensure that pharmacy benefit services provided are medically necessary;
- Promote safe and cost-effective drug therapy;
- Manage pharmacy benefit resources effectively and efficiently while ensuring that quality care is provided;
- Ensure that members can easily access prescription services;
- Actively monitor utilization to guard against over-utilization of services and fraud or abuse;

C.  AUTHORITY
Centene Corporation is a fully integrated government services managed care company with health plans in several states. Due to differences in state regulations, Centene’s Board of Directors delegates responsibility to the Plan President/CEO who coordinates the provision of pharmacy services with Centene’s contracted pharmacy benefit manager (PBM), Envolve Pharmacy Solutions. In turn, Envolve Pharmacy Solutions is contractually responsible for implementing Centene’s Pharmacy Program including benefit design, the Preferred Drug List (PDL), drug utilization review (DUR), the prior authorization process, pharmacy network management, pharmacy claims processing, pharmacy help desk, customer service functions, clinical reviews, and reporting.

Centene or its subsidiaries does not discriminate on the basis of race, color, national origin, sex, age or disability, nor exclude from participation in, deny the benefits of, or otherwise subject to discrimination under any applicable Company health program or activity.

II.  UTILIZATION MANAGEMENT GOALS AND FUNCTIONS

A.  GOALS
The goals of the Pharmacy Program are to:

- Promote pharmaceutical utilization known to improve clinical outcomes
- Monitor and evaluate the quality of the pharmacy program;
- Conduct drug utilization review (DUR) activities to monitor appropriate drug use,
- Promote cost containment without compromising quality of care;
• Identify, assess and refer members who could benefit from case management/disease management;
• Ensure confidentiality of member and practitioner information;
• Ensure timely reviews of requests for drug therapy exceptions to PDL positioned drugs;
• Ensure timely responses to appeals and grievances;

B. FUNCTIONS
The key function of the Pharmacy Program is to promote the appropriate use of the pharmacy benefit. Components of the Pharmacy Program include:
• Use of prior authorization and medical necessity criteria, concurrent and retrospective drug utilization review (DUR), and edits related to maximum dosing, early refills, age and gender, quantity limits, maximum approved costs, duplicate therapy, adverse reactions and prescriber restrictions;
• Analysis of utilization data;
• Develop, review and update policies and procedures that govern the various aspects of the pharmacy benefit;
• Identify opportunities to improve quality of care and services;
• Interface with other Health Plan departments including Medical Management, Member Services, Provider Services and Quality Improvement to support opportunities for case management, disease management, and member and provider education;
• Provide feedback to providers who demonstrate inappropriate prescribing patterns that deviate from recognized practice standards and guidelines;

III. ACCOUNTABILITY AND ORGANIZATIONAL STRUCTURE
The Health Plan’s Board of Directors has the ultimate authority and responsibility for the Pharmacy Program. The Board delegates the responsibility for the oversight of the Pharmacy Program to the Plan’s President/CEO and Chairman of the Centene Corporation Quality Improvement (QI) Council. The Pharmacy Program activities are integrated with the Health Plan’s Utilization Management (UM) and Quality Improvement (QI) Programs. The utilization and quality issues and trends identified as part of the Pharmacy Program are reported to the Health Plan QI Committee.

IV. CENTENE HEALTH PLAN’S PHARMACY AND THERAPEUTICS COMMITTEE
A. MEMBERSHIP
The Vice President of Medical Affairs (VPMA), the Chief Medical Officer or the Medical Director at the Health Plan or his/her designee will chair the Pharmacy and Therapeutics (P&T) Committee. The Health Plan Pharmacist will serve as the Secretary of the Committee. The P&T Committee addresses quality and utilization issues related to provision of the pharmacy benefit. Voting members of the Committee will include community based practitioners and pharmacists representing various clinical specialties that adequately represent the needs of Health Plan members. The community based practitioners must be independent and free of conflict with respect to the health plan and pharmaceutical manufacturers. P&T Committee meetings will be held at least quarterly.
B. RESPONSIBILITIES AND FUNCTIONS OF THE PHARMACY AND THERAPEUTICS COMMITTEE

The responsibilities of the P&T Committee may include, but are not limited to, the following:

- Objectively appraise, evaluate and recommend drugs for inclusion in or removal from the PDL consistent with providing high quality and cost-effective care while addressing safety, efficacy and pharmacoeconomics;
- Review newly FDA approved drug products within 90 days, and reach a decision for PDL positioning for each newly FDA approved drug within 180 days of their release.
- Assist in quality improvement programs that employ drug use evaluation (DUE);
- Review the policies and procedures for pharmacy benefit management activities, such as prior authorizations, medical necessity criteria, step therapies, age and gender restrictions, quantity limitations, mandatory generics and other activities that affect access, and make recommendations for changes as appropriate;
- Review the administrative policies and procedures;
- Review of individual provider prescribing for appropriate drug utilization. Egregious prescribing patterns will be reported to the Quality Initiative Department for consideration of the appropriateness of Health Plan provider credentialing;
- Review of state regulations to ensure compliance with all mandates and requirements;
- Review of complaints/appeals and grievances pertaining to the pharmacy benefit (when applicable);
- Provide oversight of the designated Pharmacy Benefits Manager (PBM), Envolve Pharmacy Solutions, to ensure that pharmacy providers contracted for provision of pharmacy services are in compliance with their contracts, and that PDL programming and other delegated responsibilities are being applied and administered in accordance with P&T recommendations;
- Review of provider requests for additions, deletions or changes to the Preferred Drug List (PDL), and forward such requests to the corporate liaison from the Pharmacy Solutions Group, after review by the Health Plan P&T Committee. The procedure for submission of provider requests is defined by corporate policy and procedure. (see Preferred Drug List Policy and Procedure, CC.PHAR.10, attachment “PDL Change Request Form”);
- Review and approve the Pharmacy Program Description at least annually;

V. PLAN PHARMACIST RESPONSIBILITIES

The Plan Pharmacist is responsible for the oversight of the Pharmacy Program and successful operation of the Health Plan Pharmacy & Therapeutics Committee in conjunction with the VP of Medical Affairs, the Chief Medical Officer or the Medical Director.

Responsibilities include:

- Review Centene P&T Committee policies to assure compliance with state rules and regulations;
- Review Centene P&T Committee clinical drug criteria, used in the prior authorization and medical necessity review process, for appropriateness and present them to the Health Plan P&T Committee for review and approval;
- Review policies and procedures developed by the corporate liaison from the Pharmacy Solutions Group and make suggestions for changes consistent with Health Plan P&T Committee recommendations and state regulations.
• Provide oversight of the designated PBM, Envolve Pharmacy Solutions, and their delegated responsibilities and programming as it applies to prior authorization, medical necessity and other pharmaceutical management edits;
• Provide a point of contact for providers calling in with questions about the Pharmacy Program and educate providers on Pharmacy Program to promote provider satisfaction;
• Call providers as necessary to discuss Pharmacy Program issues and provider complaints;
• Review and analyze Health Plan pharmacy cost and utilization reports and report on trends and initiatives for cost-containment;
• Monitor practitioner prescribing patterns and suggest corrective action, as appropriate, for providers identified with prescribing concerns related to the provision of quality care;
• Serve as a liaison between the Health Plan Pharmacy Department and other Health Plan departments and provide support to the Medical Management staff in the performance of their responsibilities;

VI. REVIEW OF PROGRAM ELEMENTS
A. DRUG UTILIZATION REVIEW (DUR) PROGRAM
The Pharmacy Program administers a retrospective drug utilization review program, delegated to the pharmacy benefit manager (PBM), Envolve Pharmacy Solutions, utilizing the standards, criteria, protocols and procedures approved by the Centene Corporate and Health Plan P&T Committees, and in accordance with applicable state and federal requirements, NCQA standards and recognized medical practice standards. DUR projects are agreed upon by the mutual consent of the corporate liaison from the Pharmacy Solutions Group, the Health Plan Pharmacy Departments and Envolve Pharmacy Solutions. Once established, Envolve Pharmacy Solutions provides the Health Plan a list of members whose prescription history deviates from the protocols of the retrospective DUR initiatives.
The goals of the DUR program include but are not limited to:
• Identify and analyze prescribing patterns, and share the information with the appropriate providers to impact prescribing, dispensing, and overall drug utilization practices;
• Identify changes in pharmacotherapy that will improve member outcomes;
• Identify poly-pharmacy, educate prescribers and share information with multiple prescribers;
• Identify medication non-adherence and report incidences to prescribers or case managers as appropriate;
• Identify and address potential member, prescriber, or pharmacy provider fraud and abuse.

B. PRIOR AUTHORIZATIONS
The Prior Authorization (PA) process was developed to promote clinically appropriate utilization of selected high risk and/or high cost medications, and those subject to a high potential for abuse. This process is delegated to Envolve Pharmacy Solutions, and administered in accordance with applicable state and federal requirements, NCQA standards and recognized high quality practice standards. The PA criteria for approval of drug coverage are developed by the Clinical Pharmacy Advisory Committee (CPAC) and reviewed and approved by both the Centene and Health Plan P&T Committees. In addition, prior authorization criteria are consistent with review of current pharmaceutical and medical literature, peer reviewed journals and professional standards of
practice. PA guidelines generally require that certain conditions be met before coverage of drug therapy can be authorized.

Envolve Pharmacy Solutions supplies the Health Plan, on a daily basis, member specific adverse coverage determinations for prior authorization or medical necessity reviews. The Health Plan then sends letters to members advising of a denial for drug coverage, an explanation on their appeal rights, and referral of the member back to the prescriber for requests for PDL alternative therapy. Envolve Pharmacy Solutions advises prescribers by fax of adverse coverage determinations with suggestions for PDL alternative therapy.

C. APPEALS AND GRIEVANCES
The Centene Health Plans will maintain an internal appeals process for the benefit of its members and will provide members affected by an adverse coverage decision with a written explanation on how to access the appeals options. Providers may also appeal an unfavorable coverage decision on behalf of members.

D. PREFERRED DRUG LIST (PDL)
The Preferred Drug List (PDL) is a listing of covered pharmacy services approved by the Centene and Health Plan P&T Committees. The PDL is posted on the Health Plan’s web site and can be downloaded and printed for future reference. It includes information on pharmaceutical management procedures, explanations of drug therapy limitations, mandatory generic substitution, prior authorization and step therapy protocols.

E. SAFETY ISSUES
The Plan designates real time adjudication of drug claims and the identification of potential adverse drug events to the Envolve Pharmacy Solutions PBM processing application. Envolve Pharmacy Solutions uses a passive system for point of dispensing communications and sends online alerts to dispensing pharmacies that identify and classify potential drug-drug interactions by severity. Envolve Pharmacy Solutions also identifies and notifies the Health Plans and pharmacy providers of Class I drug alerts and drug recalls which have the potential to cause serious health problems. When a high level of concern for safety is identified, Envolve Pharmacy Solutions supplies the Health Plan with a list of members that may be affected. After notification, it is the health plan’s responsibility to notify members and document such outreach. In certain instances, Envolve Pharmacy Solutions may be designated to carry out member and prescriber notification. Class II and III alerts are evaluated according to their potential to cause harm and generally pose minimal risks to a patient’s health, but may be acted on if judged appropriate. (See USS.PHARM.02)

F. EXCEPTIONS
The Centene and Health Plan P&T Committees must review for clinical appropriateness, the Envolve Pharmacy Solutions policies and procedures assuring timely access to both PDL and non-PDL drug products. For this reason, Envolve Pharmacy Solutions is held to strict protocols regarding the timeliness of clinical reviews. A 72-hour supply policy is in place to allow for interim therapy while a clinical review can be completed. In addition, if a member tries to obtain a non-PDL drug after hours or on holidays, the member is allowed a 72-hour supply until the Envolve Pharmacy Solutions Clinical Pharmacy Department resumes normal business hours.
NurseWise takes after-hours calls and has responsibility for approving interim 72-hour supplies. (See CC.PHAR.01 72 Hour Emergency Supply of Medication)

REFERENCES:
CC.COMP.42_ACA 1557 Nondiscrimination in Health Programs Activities

ATTACHMENTS:
N/A

DEFINITIONS:
N/A

REVISION LOG

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<thead>
<tr>
<th>REVISION</th>
<th>DATE</th>
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<tbody>
<tr>
<td>Inserted “delegated to the pharmacy benefit manager (PBM) utilizing the standards, criteria, protocols and procedures established by Centene, and in accordance with applicable State and federal requirement and NCQA standards” within the “Drug Utilization Review (DUR) Program” section.</td>
<td>06/07</td>
</tr>
<tr>
<td>Added the following bullet point under “DRUG UTILIZATION REVIEW (DUR) PROGRAM” section, “Identify and address member, prescriber and pharmacy fraud and abuse.”</td>
<td>06/07</td>
</tr>
<tr>
<td>Inserted “This process is also delegated to the PBM utilizing utilizing the standards, criteria, protocols and procedures established by Centene, and in accordance with applicable State and federal requirement and NCQA standards.” and deleted Pharmaceutical Management may be delegated to a PBM under the direction of the Centene Corporate Pharmacy Solutions within the “Prior Authorization” section.</td>
<td>06/07</td>
</tr>
<tr>
<td>Inserted the following sentence to the “Drug Utilization Review (DUR) Program section, “Each DUR project topic is selected and approved by the Health Plan prior to delegation to the PBM for completion.”</td>
<td>07/07</td>
</tr>
<tr>
<td>Omit the following sentence under the “UTILIZATION MANAGEMENT GOALS AND FUNCTIONS” “Functions” section: Review of new pharmacy utilization polices or criteria as drafted by the corporate Centene Pharmacy &amp; Therapeutics (P&amp;T) Committee or the corporate Centene pharmacy department and recommend changes as appropriate.</td>
<td>08/08</td>
</tr>
<tr>
<td>Add “Member Services” under the “UTILIZATION MANAGEMENT GOALS AND FUNCTIONS” “Functions” section where it mentions interfacing with other departments.</td>
<td>08/08</td>
</tr>
<tr>
<td>Under “CENTENE HEALTH PLAN’S PHARMACY AND THERAPEUTICS COMMITTEE” “Membership” section the following sentence was changed from “The P&amp;T Committee addresses quality and utilization issues related to provision of pharmaceuticals” to The P&amp;T Committee addresses quality and utilization issues related to provision of the pharmacy benefit”</td>
<td>08/08</td>
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<tr>
<td>Omit the following from “Functions of the Pharmacy and Therapeutics Committee”: This timeframe will also apply to FDA approved drugs that have</td>
<td>08/08</td>
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been granted new indications.

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<th>Action</th>
<th>Date</th>
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<td>Omit the following bullet point from “Clinical Pharmacist Responsibility”: Distributes at least annually and when changes are made the pharmacy management procedures to practitioners; as required by ODJFS requirements, the PDL, drugs requiring authorization and all protocols must be posted to the web for members and providers.</td>
<td>08/08</td>
</tr>
<tr>
<td>Under the Preferred Drug List section revise the paragraph from “The Preferred Drug Listing (PDL) is approved by the Corporate P&amp;T Committee. Distribution to practitioners occurs in the Provider Manual and posted on the Health Plan’s Website and includes how to use the pharmaceutical management procedures, explanation of limits and quotas, the exception process to be followed by practitioners and the organizations process for generic use and substitution, therapeutic interchange and step therapy protocols.” to “The Preferred Drug Listing (PDL) is a listing of covered pharmacy services approved by the Corporate P&amp;T Committee. The PDL is posted on the Health Plan’s Website and can be downloaded and printed along with PA forms for future reference. It includes information on pharmaceutical management procedures, explanations of prescribing limitations, mandatory generic substitution, step therapy protocols and the appeals process”</td>
<td>08/08</td>
</tr>
<tr>
<td>Under “Safety Issues” section revise the following section from “members and prescribing providers affected by Class II and Class III recalls or voluntary drug withdrawals from the market within 30 days of the FDA notification. For those drugs categorized by Class I will be subject to an expedited process of notification to members and prescribing practitioners” to “the health plans and pharmacy providers of Class I drug alerts and drug recalls which have the potential to cause serious health problems. The PBM supplies the health plan with a list of members affected and believed to be using the drug of concern. After notification, it is the health plan’s responsibility to notify members and document such outreach. Class II and III alerts are evaluated according to their potential to cause harm and are generally considered only slight risks to a patient’s health, but may be acted on if judged appropriate”</td>
<td>08/08</td>
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<tr>
<td>Added the following to the last part of the “Exceptions” section: For this reason, the PBM is held to strict protocols regarding the timeliness of clinical reviews. In addition, if a member tries to obtain a non-PDL drug after hours or on holidays, the member is allowed a 72-hour supply until a clinical review can be completed.</td>
<td>08/08</td>
</tr>
<tr>
<td>This P&amp;P was rewritten to reflect the current Centene Health Plan process, aligning with the Pharmacy Benefit Manager's process and NCQA requirements.</td>
<td>02/09</td>
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<tr>
<td>Revisions completed at this time were made to address clerical errors, align with NCQA standards and language, and represent the work processes in place at both the Plan level and at US Script.</td>
<td>02/10</td>
</tr>
<tr>
<td>No changes.</td>
<td>02/11</td>
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<tr>
<td>Renamed “Clinical Pharmacist Responsibilities” to “Plan Pharmacist Responsibilities”.</td>
<td>02/12</td>
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<tr>
<td>Defined purpose and scope as applying to members “eligible” for a pharmacy benefit.</td>
<td>02/12</td>
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<tr>
<td>02/13</td>
<td>No changes were deemed necessary.</td>
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<tr>
<td>02/14</td>
<td>Updated “Goals” to include “Promote pharmaceutical utilization known to improve clinical outcomes”.</td>
</tr>
<tr>
<td>08/14</td>
<td>No changed deemed necessary.</td>
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<tr>
<td>08/15</td>
<td>Changed “…Corporate Pharmacy Solutions” to “…the corporate liaison from the Pharmacy Solutions Group” under section IV B, bullet 10, section V bullet 3, section VI A in the first paragraph and section VI B in the body of the paragraph.</td>
</tr>
<tr>
<td>08/16</td>
<td>Annual Review</td>
</tr>
<tr>
<td>11/16</td>
<td>Changed US Script to Envolve Pharmacy Solutions; Under B. Prior Authorizations: took out reference to the “corporate liaison from the pharmacy solutions group” and replaced with “Envolve Pharmacy Solutions” as responsible for developing PA criteria; Under E. Safety Issues: indicated that Envolve Pharmacy Solutions can be designated to carry out member and provider notifications for drug recalls</td>
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<tr>
<td>11/17</td>
<td>Added discrimination statement; Updated references.</td>
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<tr>
<td>10/18</td>
<td>Annual Review – no changes.</td>
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**POLICY AND PROCEDURE APPROVAL**

The electronic approval retained in RSA Archer, the Company's P&P management software, is considered equivalent to a signature.